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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PRATS, FRANCISCO CHANDLER	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Applicati n N .	Applicant(s)	
	09/869,398	BENGS ET AL.	
	Examiner	Art Unit	
	Francisco C Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

P riod for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The preliminary amendment filed June 28, 2001, has been received and entered.

Claims 1-20 have been cancelled.

Claims 21-41 have been added.

Claims 21-41 are pending and are examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what the recitation "prebiotics" in claim 22 refers to. A holding of indefiniteness is therefore required.

Similarly, in claim 25, it is not clear what the recitation "microparticles" means. To the extent it means simply small particles, it is not clear how small the particles must be to be encompassed by the claims. The metes and bounds of "micro" are

simply not clear. Also, note that molecules themselves are in fact "microparticles."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21, 22, 24-26, 30-37 and 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Kossman et al (WO 95/31553).

Kossman describes the production of a linear α-1,4 glucan from sucrose, using amylosucrase, as recited in claim 30. See abstract. Kossman discloses that the glucan does not contain any branch points. See page 8, last sentence ("[a]ccording to the invention it could be shown that the product of the reaction catalyzed by amylosucrase are linear α-1,4 glucans ***that are not branched as has been assumed so far*** (see above)."). See also page 36, last sentence of the first paragraph ("[w]ith the available analytical methods it was not possible to detect branching in the synthesis products.") Thus, Kossman describes

the linear α-1,4 glucan product recited in applicant's claims, clearly meeting the limitation requiring less than 0.5% branch points.

Kossman also describes that the linear α-1,4 glucans prepared by amylosucrase synthesis are useful in all of the applications to which amylose, another linear α-1,4 glucan, can be put. See discussion on pages 1 and 2. The applications Kossman describes for linear α-1,4 glucans include tablet binders, food thickeners, and the formation of inclusion compounds with vitamins, pharmaceutical compounds and aromatic substances, thus anticipating the claimed uses as a carrier, as well as the "enrobed" embodiment recited in claim 26. Lastly, note that the method recited in claim 41 is inherently disclosed by Kossman's disclosure of orally acceptable compositions containing the linear α-1,4 glucans, since a person orally consuming the glucans would inherently benefit from the preventive effect of the glucans. Thus, because Kossman clearly describes the claimed invention, rejection under § 102(b) is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 21 and 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kossman et al (WO 95/31553).

As discussed above, Kossman describes the production of a linear α-1,4 glucan from sucrose, using amylosucrase, and the use of the glucan in foods and pharmaceuticals.

Kossman differs from the claims in that Kossman does not disclose the molecular weight of the glucans, as recited in claims 27-29. However, the artisan of ordinary skill clearly would have recognized that molecular weight would be a function

of the duration of the synthetic reaction catalyzed by amylosucrase (see page 7, equation at bottom of the page). Moreover, the artisan of ordinary skill clearly would have been able to readily determine molecular weights of the glucan suitable for the various applications disclosed in Kossman. Thus, the selection of specific molecular weights of the glucans disclosed in Kossman, recited in applicant's claims 27-29, must be considered obvious in view of Kossman's disclosure. A holding of obviousness under § 103(a) is therefore required.

Claims 21-23 and 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kossman et al (WO 95/31553) in view of Brown (WO 96/082610.

As discussed above, Kossman describes the production of a linear α-1,4 glucan from sucrose, using amylosucrase, and the use of the glucan in foods and pharmaceuticals.
Kossman differs from the claims in that Kossman does not disclose the use of the glucan as a carrier when the beneficial agent is bifidobacteria, as recited in claims 23 and 38.
However, Brown discloses a pharmaceutical composition beneficial to the gastrointestinal tract, said composition comprising high amylose starch and bifidobacteria. See abstract. Brown also discloses that starches containing over %80 amylose (i.e., over

%80 linear α-1,4 glucan) are preferred. See, e.g., claim 5 on page 26. Further still, Kossman clearly discloses that his linear, unbranched α-1,4 glucans, are suitable for use in applications to which amylose can be put. See discussion on pages 1 and 2 of Kossman.

Thus, the artisan of ordinary skill, recognizing from Kossman that linear, unbranched α-1,4 glucans are suitable for use as carriers for beneficial agents, clearly would have been motivated to have used Kossman's glucans as carriers for Brown's bifidobacteria. Specific motivation would have been derived from Brown's disclosure of the desirability of combining the bifidobacteria with high amylose starch, the artisan of ordinary skill clearly recognizing that Kossman's glucans were in fact identical to pure amylose, and therefore well within the at least %80 amylose disclosed by Brown as being desirably combined with the bifidobacteria. A holding of obviousness under § 103(a) is therefore clearly required.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner

can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Francisco C Prats
Primary Examiner
Art Unit 1651

FCP
May 7, 2003